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10/799,431

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Herbert Chao

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COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER

PALENIK, JEFFREY T

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/799,431 | Applicant(s) CHAO ET AL. | |
| | Examiner Jeffrey T. Palenik | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>27 Apr 2004 and 22 June 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their reply as discussed within the Interview Summary dated 21 February 2008, in the matter of 10/799,431.

Applicants' election **with traverse** of Group I, claims 1-22 is acknowledged.

Regarding the election of Group I, Applicants' arguments have been considered but are not persuasive. Applicants traverse the restriction on the grounds that the remaining claims 23-30 are not directed to one or more independent and distinct inventions.

The Examiner respectfully disagrees and maintains the restriction on the grounds that the Groups are directed to independent and distinct inventions, particularly in view of the recitations in Group III (claim 29) and Group IV (claim 30). Group III is directed at using the article of claim 23. However, the article of claim 23 only comprises (i.e. is formed from) the composition of claim 1. Given the breadth of the components of claim 1, namely the at least one or more active agent(s) infused into the elastomeric matrix, and "a carboxyl-terminated polymer" as it is further defined in claims 3, 4, and 8, it follows that independent and chemically distinct elastomeric matrices are conceived which do not necessarily overlap in scope as further evidenced by the instantly claimed method for providing different chemical effects as recited in claim 29.

In view of the forgoing, the requirement is deemed proper and is therefore made **FINAL**.

The remaining claims 1-22 are presented and represent all claims under consideration.

Information Disclosure Statement

Two Information Disclosure Statement (IDS), filed 27 April 2004 and 22 June 2005, are

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acknowledged and have been reviewed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ratio limitations recited in claims 2 and 6 render the claims indefinite because it is not clear what ratio range is being claimed. For example, claim 2 recites that the ratio of polycarbodiimide to carboxyl-terminated polymer is 0.7 to 6.0. It is not clear to the Examiner whether Applicants intended this to be interpreted as 0.7:1 to 6:1 or if it is to be interpreted as 0.7:6.0.

Claims 10-12 recite the limitation "the carboxyl-terminated copolymer" in the first line of each claim. There is insufficient antecedent basis for each of these limitations in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 10-16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapin et al. (USPN 4,594,380).

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The instant claims are directed to a continuous-release composition comprising an elastomeric matrix and at least one active agent wherein said matrix is the reaction product of a carboxyl-terminated polymer and a polycarbodiimide (claims 1, 2, 6, 10-12, 14 and 22). With regard to the limitation of claim 1, wherein “the active agent being released from the matrix into the environment substantially continuously over an extended period of time”, is considered by the Examiner as a functional limitation of the instantly claimed composition; it is a limitation expected of a continuous release composition. With regard to the limitations respectively recited in claims 2 and 6, which state “wherein the ratio of polycarbodiimide to carboxyl-terminated polymer is 0.7 to 6.0” and “...is 0.7 to 1.4”, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the elastomeric matrix composition which is instantly claimed. Regarding the limitation of claims 10-12 wherein the carboxyl terminated copolymer of claim 1 is the reaction product of a mixture...”, is deemed by the Examiner as being a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Regarding the limitations recited in claims 11 and 12 which are directed to the percent composition of the carboxyl-terminated copolymer, said recitations are deemed by the Examiner as being functional limitations to product-by-process limitations and similarly hold no patentable weight. The functionality limitation as recited in claim 14, is considered an inseparable property of the polycarbodiimide component of the matrix composition (see MPEP §2112.01(II)). The limitation “in the form of a gel” recited in claim 22 is deemed one of intended use and holds no patentable weight with regards to the instantly claimed composition. Hydrophobic carboxyl-terminated polymers are recited (claim 3). Types of polycarbodiimides used are recited (claim 13). The composition further comprising one or more inert (e.g. non-biologically active) agents is recited (claims 15 and 16). Dissolution or

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dispersal of the active agent(s) in the matrix is recited (claims 18 and 19). Percentage of the active(s) in the matrix is recited (claim 20). A fragrance as the active agent(s) is recited (claim 21).

Chapin et al. teach an article comprising an elastomeric matrix and at least one biologically or non-biologically active agent in the matrix which is continuously released over an extended period of time (claim 1). Said matrix is taught as comprising polyurethane which is formed by reacting a polyol with an isocyanate (claim 1). Though the term “polycarbodiimide” is not expressly used in the teachings of Chapin, the polyurethane which is formed from the reaction of Chapin in claim 1, is polycarbodiimide as defined by Torimae et al. (USPN 4,221,572) wherein the toluene diisocyanate and polyols are reacted to form polycarbodiimide compounds (Abstract and Example 1). The same reaction is performed by Chapin wherein the reacted polyol comprises hydroxyl-terminated and carboxyl-terminated components and the isocyanates used comprise aromatic, aliphatic, cycloaliphatic and heterocyclic isocyanates having functionalities greater than 2 (e.g. between 2 and 3) (claims 1 and 2). The instantly claimed hydrophobic carboxyl-terminated polymers are taught in claim 2. The polyol taught in claim 1 is taught as a copolymer of hydroxyl- and carboxyl-terminated polymers, the resulting copolymer having a molecular weight ranging from 400-10,000. Claim 3 teaches the composition as further comprising inert components such as fillers, plasticizers, stabilizers, pigments and fungicides. Claim 4 teaches fragrances (e.g. deodorants, air fresheners, perfumes, attractants and repellents) as the active agent. Claims 9 and 10 respectively teach the active agent as being dissolved and dispersed in the matrix. Claim 8 teaches the active agent as comprising 10-50% by weight of the article.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapin et al. (USPN 4,594,380) in view of Riew et al. (USPN 3,966,837) and in further view of *Hawley's Condensed Chemical Dictionary*, (13th Edition).

The instant claims are directed to an active agent-infused, continuous-release, elastomeric matrix composition, as discussed above. Claim 4 recites species of the claimed hydrophobic carboxyl-terminated polymer and that it is a major component of the composition. Claim 5 further limits the "major component" as comprising at least 90% by weight of the composition. Claim 7 recites that the hydrophobic carboxyl-terminated polymer as having an average molecular weight ranging from 1,000 to 20,000. Claims 8 and 9 recite that the carboxyl-terminated polymer is hydrophilic, is a major component of the composition (e.g. 90% by weight or more) and consists of carboxyl-terminated polyethylene oxides or carboxyl-terminated polyether polyols. Claim 17 recites the carboxyl-terminated polymer of claim 1 as having a

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molecular weight ranging from 1,000 to 10,000 and that it is a carboxyl-terminated polybutadiene or carboxyl-terminated isoprene. The average carboxylic acid functionality limitation as recited in claim 17, is considered an inseparable property of the carboxyl-terminated polymer component of the matrix composition (see MPEP §2112.01(II)).

The teachings of Chapin et al. are discussed above. Chapin further teaches the instantly claimed species of hydrophobic carboxyl-terminated polymer (e.g. carboxyl-terminated polybutadiene) compounds as well as the polyol, which comprises both hydroxyl- and carboxyl-terminated polymers as having a molecular weight ranging from 400 to 10,000 (claims 1 and 2).

However, Chapin does not expressly teach hydrophilic carboxyl-terminated polymers. Nor are carboxyl-terminated polymers, in general, taught as comprising the major component (e.g. 90% by weight or more) of the matrix composition.

Riew et al. teach increasing the strength and rigidity of synthetic resin products by using different functionally terminated elastomers such as copolymers of carboxyl-terminated isoprene and acrylonitrile and carboxyl-terminated polybutadiene (Example 6). Functionally terminated polyethers or polyethylene oxide are also taught in Example 6, wherein it is preferred that said functionally reactive groups be carboxyl groups (col. 3, lines 8-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a fragrance-infused, continuous-release, elastomeric matrix composition comprising either a hydrophilic or hydrophobic carboxyl-terminated polymer, as suggested by

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Chapin et al. and Riew et al., modify the levels of the selected carboxyl-terminated polymer such that it comprises 90% by weight or more (e.g. the major component), and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the inventions practiced by both Chapin et al. and Riew et al. are directed to teaching how to strengthen synthetic polymeric matrix materials by using functionally terminated elastomeric compounds. While Chapin does not expressly teach incorporating hydrophilic carboxyl-terminated polymers comprising PEO or polyether polyols, Riew does teach them as well as the hydrophobic carboxyl-terminated polymers and copolymers of the instant claim 4, thereby expressly teaching that the elastomers are directed towards establishing the same functional property within their respective elastomeric matrices.

Neither of the references expressly teaches either the hydrophobic or hydrophilic carboxyl-terminated polymers as comprising 90% or more of the elastomeric composition by weight, as instantly claimed by Applicants. Since the values and formats of each parameter with respect to the claimed invention are interchangeable or adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize in order to best achieve the desired fragrance-infused, controlled-release, elastomeric composition. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, reverse the composition of the major and minor components of the polyol component of the composition practiced by Chapin. *Hawley's Condensed Chemical Dictionary*, defines a carboxyl group as a functional group which is typically used as a terminal group and is capable of assuming a negative charge, which makes the molecule to which it is attached, water-soluble or hydrophilic.

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It is further taught that the carboxyl group is composed of a carbonyl group with a hydroxyl group attached to it, thereby also classifying it as a “hydroxyl-terminated” functional group.

Thus, in further view of *Hawley's*, one of ordinary skill in the art would have been motivated to adjust the levels of two chemically similar “hydroxyl-terminated” components in order to achieve the desired product. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 10-16 and 18-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 8-10 of Chapin et al. (USPN 4,594,380). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims practiced in the '380 patent are obvious variants, if not anticipatory, of the currently presented claims. The subject matter recited by the instant claims 1, 2, 6, 10-14 and 22 are combined within and read upon by claims 1 and 2 of the '667 patent. The remaining claims 2, 6, 10-12, 14 and 22 are discussed above as reciting the same subject matter as the instant claim 1 in view of their limitations. The carboxyl-terminated species recited in the instant claims 3 and 4 are read on and rendered obvious by claim 2. The inert components recited in the instant claims 15 and 16 are read upon and rendered obvious by claim 3 of the '380 patent. The "dissolved" and "dispersed" within the matrix limitations of the instant claims 18 and 19 are read upon by claims 9 and 10 of the '380 patent. The percentage of active agent recited in claim 20 is read upon and anticipated by claims 8 and 12 of the '380 patent. The fragrance limitation recited in the instant claim 21 is read on and rendered obvious by claim 4 of the '380 patent. The key difference between the instant claims and the conflicting claims of the '380 patent is that the carboxyl-terminated polymers, as claimed are taught as the minor component as opposed to their recitation as the major component of the composition (see instant claim 4 versus '380 claim 2). Despite this difference one of ordinary skill in the art would have immediately recognized the obvious overlap in subject matter and would have been motivated with a high expectation of success, to practice the instant invention.

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All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.

The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615